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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/525,145	10/06/2005	Hiroshi Shiku	3400.P1417US	5607
23474 7590 10/09/2007 FLYNN THIEL BOUTELL & TANIS, P.C. 2026 RAMBLING ROAD KALAMAZOO, MI 49008-1631			EXAMINER JUEDES, AMY E	
			ART UNIT 1644	PAPER NUMBER
			MAIL DATE 10/09/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/525,145

Applicant(s)

SHIKU, HIROSHI

Examiner

Amy E. Juedes, Ph.D.

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1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 20-39 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Restriction is required under 35 U.S.C. 121 and 372.
2. This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.
3. In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Claims 20-21 link(s) inventions 1-8. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s) 20-21. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Groups 1-4, claims 22-27, 30-31, and 33-36, drawn a method of immunosuppressing a mammal comprising administering an antigen recognized by a CD4+CD25+ regulatory T cell, wherein groups 1-4 correspond to the antigens DnaJ-like2, Galectin-8, poly(A)-binding protein, and Ligase-1, respectively.

Group 5-8, claims 22-26, 28-29, 32-39, drawn a method of immunosuppressing a mammal comprising administering an expression vector encoding an antigen recognized by a CD4+CD25+ regulatory T cell, wherein groups 5-8 correspond to the antigens DnaJ-like2, Galectin-8, poly(A)-binding protein, and Ligase-1, respectively.

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4. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Irrespective of the group elected, Applicant is further required to elect:

a specific cytokine or combination of cytokines to be administered, from the group consisting of interferon- γ or interleukin 12 and interleukin 18,

a specific method of immunosuppression, which is used to treat one of the conditions recited in claims 24-26,

and list all claims readable thereon including those subsequently added.

5. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

6. The inventions listed as Groups 1-8 and the species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reason:

The inventions of Groups 5-8, the methods for immunosuppressing a mammal, have no special technical feature that defined the contribution over the prior art of Nishikawa et al., 2001 (of record).

Nishikawa et al. teach a method comprising administering to a mammal an expression vector encoding antigens identified by the SEREX method, including the antigens DnaJ-like2, Galectin-8, poly(A)-binding protein, and Ligase-1 (i.e. antigens recognized by CD4+CD25+ regulatory T cells, see page 14572 in particular).

7. Since Applicant's inventions do not contribute a special technical feature when viewed over the prior art they do not

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have a single general inventive concept and so lack unity of invention.

8. Accordingly, Groups 1-8 are not so linked as to form a single general inventive concept and restriction is proper.


9. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E. Juedes, Ph.D. whose telephone number is 571-272-4471. The examiner can normally be reached on 8am - 5pm, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Amy Juedes, Ph.D.
Patent Examiner
Technology Center 1600


9/27/09
G.R. EWOLDT, PH.D.
PRIMARY EXAMINER